

REMARKS

Applicants respectfully request reconsideration of this application in view of the foregoing amendments and the following remarks.

I. Introductory Remarks

Upon entry of the foregoing amendments, claims 10, 23-24 and 26-29 will remain pending in the application. No claims are being canceled or added. Claims 10 and 28 currently are being amended. Exemplary support for the amendment to claim 10 exists in the specification at page 22, lines 1-4, page 27, lines 3-10 and page 100, line 20 – page 101, line 19. Claim 28 is rewritten in independent form; the amendment does not introduce any substantive changes.

II. The Claims Comply with the Written Description Requirement

Claims 10, 23-24, 26-27 and 29 were rejected for allegedly failing to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. In particular, the Office stated that the claims “encompass significant structural dissimilarity and diversity as compared to the ALK-7 protein (SEQ ID NO: 2)” and that the specification does not describe a representative number of ALK-7 polypeptides. Applicants respectfully traverse the rejection.

The full-length ALK-7 protein described in the application is representative of the genus being claimed. The genus is unified by significant structural similarity to the full-length ALK-7 protein *and*, as now amended, by the requirement for kinase catalytic activity. All members of the genus must have 95% identity to the full length ALK-7 protein, must have the entire catalytic domain of the ALK-7 protein, or must have the cytoplasmic domain of the ALK-7 protein (which encompasses the entire catalytic domain). The procedures for making variants of SEQ ID NO: 2 that meet these structural criteria are conventional in the art. All members of the genus also must possess kinase catalytic activity. Assays for determining that a given variant of SEQ ID NO: 2 possesses kinase catalytic activity also are conventional in the art and described in the present application. For example, kinase activity can be measured on standard substrates such as histones, myelin basic protein, gamma tubulin

and centrosomal proteins. (Specification, page 101, lines 10-14). Given these facts, one of skill in the art would conclude that Applicants were in possession of the necessary common attributes possessed by members of the claimed genus. This situation is analogous to that set forth in Example 14 of the Revised Interim Written Description Guidelines Training Materials (copy attached), where the invention was determined to satisfy the written description requirement.

Contrary to the rejection, therefore, the claims do not “encompass significant structural dissimilarity and diversity as compared to the ALK-7 protein.” The described full-length ALK-7 polypeptide is representative of the entire claimed genus. Accordingly, Applicants request withdrawal of the written description rejection.

III. Objection to Claim 28

The Office objected to claim 28 for being dependent from a rejected base claim, but indicated that the claim would be allowable if rewritten in independent form.

Accordingly, Applicants have rewritten claim 28 in independent form, and respectfully request allowance of it.

IV. Concluding Remarks

This application is now in condition for allowance, and Applicants respectfully request favorable reconsideration of it.

If the Examiner believes that an interview would advance prosecution of the application or help to clarify issues pertaining to prosecution, he or she is invited to contact the undersigned attorney by telephone.

The Commissioner is hereby authorized to charge any additional fees that may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to

Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of any extension fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date

2/16/06

By



Beth A. Burrous
Attorney for Applicant
Registration No. 35,087

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5475
Facsimile: (202) 672-5399

Example 14: Product by Function

Specification: The specification exemplifies a protein isolated from liver that catalyzes the reaction of A → B. The isolated protein was sequenced and was determined to have the sequence as set forth in SEQ ID NO: 3. The specification also contemplates but does not exemplify variants of the protein wherein the variant can have any or all of the following: substitutions, deletions, insertions and additions. The specification indicates that procedures for making proteins with substitutions, deletions, insertions and additions is routine in the art and provides an assay for detecting the catalytic activity of the protein.

Claim:

A protein having SEQ ID NO: 3 and variants thereof that are at least 95% identical to SEQ ID NO: 3 and catalyze the reaction of A → B.

Analysis:

A review of the full content of the specification indicates that a protein having SEQ ID NO: 3 or variants having 95% identity to SEQ ID NO: 3 and having catalytic activity are essential to the operation of the claimed invention. The procedures for making variants of SEQ ID NO: 3 are conventional in the art and an assay is described which will identify other proteins having the claimed catalytic activity. Moreover, procedures for making variants of SEQ ID NO: 3 which have 95% identity to SEQ ID NO: 3 and retain its activity are conventional in the art.

A review of the claim indicates that variants of SEQ ID NO: 3 include but are not limited to those variants of SEQ ID NO: 3 with substitutions, deletions, insertions and additions; but all variants must possess the specified catalytic activity and must have at least 95% identity to the SEQ ID NO: 3. Additionally, the claim is drawn to a protein which **comprises** SEQ ID NO: 3 or a variant thereof that has 95% identity to SEQ ID NO: 3. In other words, the protein claimed may be larger than SEQ ID NO: 3 or its variant with 95% identity to SEQ ID NO: 3. It should be noted that “having” is open language, equivalent to “comprising”.

The claim has two different generic embodiments, the first being a protein which comprises SEQ ID NO: 3 and the second being variants of SEQ ID NO: 3. There is a single species disclosed, that species being SEQ ID NO: 3.

A search of the prior art indicates that SEQ ID NO: 3 is novel and unobvious.

There is actual reduction to practice of the single disclosed species. The specification indicates that the genus of proteins that must be variants of SEQ ID NO: 3 does not have substantial variation since all of the variants must possess the specified catalytic activity and must have at least 95% identity to the reference sequence, SEQ ID NO: 3. The single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO: 3 which are capable of the specified catalytic activity. One of skill in the art would conclude that

applicant was in possession of the necessary common attributes possessed by the members of the genus.

Conclusion: The disclosure meets the requirements of 35 USC §112 first paragraph as providing adequate written description for the claimed invention.